

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION**

LUZ LECHUGA,)	
)	Case No. 5:17-cv-00728-DAE
)	
Plaintiff,)	
)	
v.)	JURY TRIAL DEMANDED
)	
BOEHRINGER INGELHEIM)	
PHARMACEUTICALS, INC.;)	
BOEHRINGER INGELHEIM PHARMA)	
GMBH & CO. KG;)	
BOEHRINGER INGELHEIM)	
INTERNATIONAL GMBH; and)	
ELI LILLY & COMPANY,)	
)	
Defendants.)	
)	

**DEFENDANTS BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. AND
ELI LILLY AND COMPANY'S REPLY IN SUPPORT OF MOTION TO DISMISS
PLAINTIFF'S COMPLAINT**

Plaintiff's Response in Opposition to Defendants' Memorandum in Support of Motion to Dismiss [D.E. 18] ("Opposition" or "Opp'n") fails to cure her Complaint's defects to survive Defendants' challenge under Federal Rule of Civil Procedure 12(b)(6) and, indeed, only underscores the deficiencies in her Complaint. Rather than respond to Defendants' arguments, Plaintiff strings together conclusory allegations and declares that she has done what is needed to survive dismissal on the pleadings. But declaring that a Complaint is adequately pleaded does not make it so. For the reasons set forth in Defendants' Memorandum in Support of Motion to Dismiss [D.E. 11] ("Defs. Mem."), Defendants respectfully request that this Court grant their Motion to Dismiss in its entirety.

I. THE DISCOVERY RULE DOES NOT SAVE PLAINTIFF'S TIME-BARRED CLAIMS.

Plaintiff does not dispute that the two-year statute of limitations for personal injury actions applies to all of her claims. Opp'n at 4. Attempting to flout the default rule that the statute of limitations accrues "from the time of injury," Defs. Mem. at 1, 4, Plaintiff invokes the discovery rule, claiming she had "no way of attributing her renal failure to the ingestion of defendants' product." Opp'n at 6.¹ However, the discovery rule only applies when the nature of the injury is "inherently undiscoverable," and neither Plaintiff's Complaint nor her Opposition explains why she could not have learned of Defendants' alleged acts or omissions within the limitations period. *Howard v. Fiesta Texas Show Park, Inc.*, 980 S.W.2d 716, 720 (Tex. App. 1998).² In short, Plaintiff's Opposition provides no reason why hers is one of the "rare" cases to

¹ Plaintiff's Complaint only alleges that Plaintiff developed diabetic ketoacidosis ("DKA") after taking Jardiance, *see, e.g.*, Compl. ¶¶ 4, 37, and not renal failure.

² In fact, Plaintiff's Opposition argues that the timing of Plaintiff's alleged injuries, which allegedly occurred unexpectedly only "five days" after she began taking Jardiance (Opp'n at 1, 5, 10), suggests a causal association between her use of Jardiance and her alleged injury, yet

which the limited exception to the accrual rule should apply. *Childs v. Haussecker*, 974 S.W.2d 31, 36 (Tex. 1998).³

Contrary to Plaintiff's assertion that the Court cannot decide whether the statute of limitations bars Plaintiff's claims at the pleadings stage,⁴ "[a] statute of limitations may support dismissal under Rule 12(b)(6) where it is evident from the plaintiff's pleadings that the action is barred and the pleadings fail to raise [sic] some basis for tolling." *Mitts v. Sikorsky Aircraft Corp.*, No. CV H-10-5164, 2012 WL 12893657, at *2 (S.D. Tex. June 26, 2012); *accord Drake v. Fitzsimmons*, No. 3:12-CV-1436-B, 2013 WL 775354, at *2 (N.D. Tex. Mar. 1, 2013).

Because Plaintiff's Complaint does not plead any facts to support her argument that the limitations period was tolled beyond her alleged diagnosis of DKA on July 29, 2015, the Court should dismiss all of Plaintiff's claims as facially time-barred. *See* Defs. Mem. at 4-5.

II. PLAINTIFF DOES NOT AND CANNOT ALLEGE AN EXCEPTION TO SECTION 82.007.

Plaintiff acknowledges that section 82.007 of the Texas Civil Practice & Remedies Code applies to her failure-to-warn claims. Opp'n at 6-8. Pursuant to section 82.007(a), Jardiance's

Plaintiff fails to explain how that same timing was insufficient to put her on notice that Jardiance may have been a potential cause of those same alleged injuries. *See* Opp'n at 2. This Court should see through the inconsistency in Plaintiff's position and hold that the limitations clock began running on the date that Plaintiff developed her alleged injury.

³ Plaintiff's reliance on *Brandau v. Howmedica Osteonics Corp.*, 439 F. App'x 317, 322 (5th Cir. 2011) and *Woodruff v. A.H. Robins Co.*, 742 F.2d 228 (5th Cir. 1984) is misplaced, because both of those cases involved implanted devices, as opposed to a prescription medication like Jardiance. *See* Opp'n at 4-5.

⁴ The case Plaintiff cites in support of this argument does not require a different result, because it did not concern the application of a statute of limitations defense at the pleading stage. Rather, the Fifth Circuit analyzed the status of an employee for purposes of Title VII protections, which the Court called a "fact-specific inquiry." *Muhammad v. Dallas Cty. Cmty. Supervision & Corr. Dep't*, 479 F.3d 377, 382 (5th Cir. 2007). This, of course, is a far different inquiry than the objective determination of the timeliness of Plaintiff's Complaint in this matter, which is the matter before this Court.

FDA-approved warning label is presumed adequate, unless Plaintiff plausibly pleads that one of the five narrow exceptions to the statute applies. Defs. Mem. at 6-10. The only exception to section 82.007(a)'s presumption of adequacy that Plaintiff attempts to allege is the fraud-on-the-FDA exception, which requires Plaintiff to allege facts showing that Defendants "withheld from or misrepresented to the [FDA] required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." Tex. Civ. Prac. & Rem. Code § 82.007(b)(1).⁵

Plaintiff challenges Defendants' assertion that the fraud-on-the-FDA exception is preempted "unless the FDA itself has found fraud." Defs. Mem. at 10. But Plaintiff's position—that the fraud-on-the-FDA exception is only preempted when the FDA has explicitly considered and rejected the underlying allegations of fraud (Opp'n at 7)—has been expressly rejected by the Fifth Circuit:

In cases like this, where the FDA has not found fraud, the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities. Under such circumstances *Buckman* found a violation of the Supremacy Clause. Thus, § 82.007(b)(1), is preempted unless the FDA itself has found fraud.

Lofton v. McNeil Consumer & Specialty Pharm., 672 F.3d 372, 380 (5th Cir. 2012). As the Fifth Circuit noted—and contrary to Plaintiff's argument—a defendant need not prove that the FDA has considered the specific allegations of fraud at issue in the underlying case. *Id.* at n.4. To the contrary, "it is now well-established that, to prove such fraud-on-the-FDA, the [p]laintiff must show that the FDA, itself, has pursued [d]efendants and prevailed on such claims of violations of

⁵ This "fraud-on-the-FDA" exception requires Plaintiff to "establish[]" that (1) a defendant withheld or misrepresented information to the FDA; (2) the FDA "required" the information; (3) the information was "material and relevant" to the drug's performance; and (4) the information was "causally related" to plaintiff's alleged injuries. Tex. Civ. Prac. & Rem. Code § 82.007(b)(1).

the federal law governing disclosures and reports on regulated pharmaceuticals.” *Jackson v. Wyeth LLC*, No. 2:12-cv-196, 2015 WL 363513, at *2 (S.D. Tex. Jan. 27, 2015).

Plaintiff’s handful of conclusory allegations that Defendants provided “false and misleading information” regarding Jardiance’s safety to “regulatory agencies” are insufficient to meet her pleading burden. Opp’n at 7-8. This is because Plaintiff’s fraud-on-the-FDA allegations sound in fraud and therefore must be plead with particularity under Rule 9(b). *See* Defs. Mem. at 18-19 (claims sounding in fraud must be stated “with particularity”). To satisfy Rule 9(b)’s particularity requirement, Plaintiff must plead the “time, place and contents of the false representations, as well as the identity of the person making the misrepresentation and what [that person] obtained thereby.” *Woodhouse v. Sanofi-Aventis U.S. LLC*, No. EP-11-CV-113-PRM, 2011 WL 3666595, at *5 (W.D. Tex. June 23, 2011). Plaintiff’s Complaint is devoid of particular facts regarding Defendants’ alleged misrepresentations to the FDA, and therefore should be dismissed with prejudice. *See, e.g., Willis v. Schwarz-Pharma, Inc.*, 62 F. Supp. 3d 560, 568 (E.D. Tex. 2014) (finding fraud-on-the-FDA allegations insufficient where plaintiff did “not provide[] any specific evidence to support th[e] allegation” that “[defendant] misled the FDA by withholding research data”); Order on Motion to Dismiss, *Quintanilla v. Bristol-Myers Squibb Co.*, Case No. 2:16-cv-00172 [D.E. 27] (S.D. Tex. Oct. 25, 2016) at 5 (allegations “devoid of any factual description” insufficient to make out exception to section 82.007(a)).

Moreover, contrary to Plaintiff’s argument that *Lofton* is inapplicable because it was decided at the summary judgement stage, Opp’n at 7, a number of courts have dismissed claims similar to Plaintiff’s at the pleadings stage for failing to plausibly plead that the FDA itself found fraud. *See, e.g., Elmazouni v. Mylan, Inc.*, 220 F. Supp. 3d 736, 743 (N.D. Tex. 2016) (dismissing failure-to-warn claims that were insufficient to allege that FDA found fraud under

Lofton); *see also* *Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 976 (S.D. Tex. 2012) (dismissing failure-to-warn claims on motion to dismiss because plaintiff had not alleged that the FDA itself found fraud); *Gonzalez v. Bayer Healthcare Pharm., Inc.*, 930 F. Supp. 2d 808, 821 (S.D. Tex. 2013) (granting motion to dismiss where plaintiff “failed to show that the FDA found fraud . . . nor identified any other exception that might apply to her case.”).

Because Plaintiff does not and cannot allege that the FDA itself has ever determined that Defendants committed fraud, all of Plaintiff’s claims challenging the adequacy of Jardiance’s warnings should be dismissed with prejudice pursuant to section 82.007(a)(1).

III. PLAINTIFF’S OPPOSITION FAILS TO SALVAGE HER INSUFFICIENTLY- PLED COMPLAINT.

Rather than point to any factual content to “allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged,” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)), Plaintiff’s Opposition states in conclusory fashion that “[t]he Complaint states a claim for relief under each theory of liability, with respect to each defendant” reiterating the same unsupported allegations with little to no supporting case law bolstering her unsubstantiated arguments. Opp’n at 1. Such an assertion fails to satisfy the pleading requirements under Rules 8(a) and 9(b) or under *Twombly* and *Iqbal*.

a. Plaintiff’s Opposition Fails To Identify Factual Allegations That Support Her Failure-to-Warn Claims (Count II, IV).

Plaintiff’s Opposition does not provide a basis for saving her warnings claims, because Plaintiff has not alleged facts identifying the inadequate warnings or how such warnings were inadequate.

Plaintiff relies on *Darbro v. Boehringer Ingelheim Pharm.*, No. CV 16-57-HRW, 2017 WL 1217161 (E.D. Ky. Mar. 31, 2017) in support of her refusal to include facts in support of her claims. Opp’n at 2.⁶ Unsurprisingly, Plaintiff does not attempt to distinguish or even address the cases cited by Defendants, which involved complaints that were strikingly similar to Plaintiff’s Complaint and provided detailed analyses as to why those complaints failed to satisfy federal pleading requirements. *See Fleming v. Janssen Pharm., Inc.*, 186 F. Supp. 3d 826, 835-36 (W.D. Tenn. 2016); *House v. Bristol-Myers Squibb Co.*, No. 15-cv-894, 2017 WL 55876, at *1, *4 (W.D. Ky. Jan. 4, 2017). Nor does Plaintiff attempt to distinguish or address the cases decided under Texas law that dismissed complaints containing similar conclusory allegations. Defs. Mem. at 11-12. Instead, Plaintiff merely reiterates her poorly pled allegations, claiming she has “clearly” met her pleading burden. Opp’n at 10-11. This is not enough, and the Court should dismiss Plaintiff’s failure-to-warn allegations.

Further, Plaintiff’s Opposition fails to respond to Defendants’ arguments that Plaintiff cannot recover under a failure-to-warn theory for conditions she did not experience, Defs. Mem. at 12. Because Plaintiff fails to address this argument, she has waived opposition to the argument, and her failure-to-warn claims should be dismissed to the extent they are based on Defendants’ alleged failure to warn of conditions Plaintiff did not experience.

b. Plaintiff Has Not Shown How Jardiance Is Defective And Her Design Claims Fail (Count I, IX).

Plaintiff agrees that, in order to state a design-based claim, she must allege both that Jardiance was unreasonably dangerous and that there was a safer alternative design that was

⁶ To the extent the Court is inclined to look to other federal district court decisions under Fed. R. Civ. P. 8 and 9, the *Darbro* decision declined to provide a substantive analysis of the law as applied to the plaintiff’s claims. The *Fleming* and *House* decisions, on the other hand, were based on detailed, substantive analyses of the plaintiffs’ claims under federal pleading requirements and law applicable to their claims.

technologically and economically feasible that would have prevented Plaintiff's alleged injury. Opp'n at 8-10. Instead of meeting these requirements, however, Plaintiff's Opposition merely reiterates her insufficiently pled allegations, Opp'n at 9, failing to address the two cases cited by Defendants, which found that the same mechanism of action alleged by Plaintiff was too "generic" to allow two different federal courts to "reasonably infer . . . that [the SGLT-2 inhibitor at issue] was defective or unreasonably dangerous." Defs. Mem. at 13.

Plaintiff essentially concedes that her Complaint has not alleged a safer alternative *design* for Jardiance. Rather, she has only alleged alternative *products* in an attempt to satisfy the pleading requirements for her design-based claims. Opp'n at 9. Under Texas law, this is insufficient, and Plaintiff's claims should be dismissed with prejudice. *See* Defs. Mem. at 13-14.

Finally, Plaintiff concedes that comment k shields Defendants from strict design defect liability, where Defendants "properly designed, marketed, and provided adequate warnings" for Jardiance. Opp'n at 10. As discussed *supra* at 2-5 and in Defendants' Memorandum, Plaintiff's Complaint lacks any factual allegations to rebut the presumptive adequacy of Jardiance's warnings or to suggest that the Jardiance Plaintiff allegedly ingested was improperly prepared. Accordingly, the Complaint does not plead that Jardiance was unreasonably dangerous and Plaintiff's design-based claims must be dismissed with prejudice.

c. Plaintiff's Opposition Does Not Identify Any Factual Allegations That Support Her Negligence-Based Claims (Counts III and IV).

Plaintiff's Opposition does not dispute that her catch-all negligence and gross negligence claims premised on an alleged failure to provide a complete and accurate warning must be dismissed under section 82.007(a) for the same reasons as her failure-to-warn claims. *Compare* Defs. Mem. at 15-16 *with* Opp'n at 11-12.

Plaintiff's Opposition outlines the legal elements of negligence, Opp'n at 11, but fails to point to any factual allegations in her Complaint, presumably because there are no such facts. Moreover, Plaintiff fails to address two arguments related to her "catch-all" negligence claim. Plaintiff does not respond to Defendants' argument that she cannot recover for a negligent manufacturing claim, because she does not allege any facts regarding "how the Jardiance she ingested 'deviate[d] in its construction or quality, from the specifications or planned output in a manner that render[ed] [Jardiance] unreasonably dangerous.'" Defs. Mem. at 16. Nor does she address Defendants' argument that she cannot maintain a negligent testing claim, because she "does not plead any facts to support' these allegations." *Id.*⁷

d. Plaintiff's Opposition Fails to Identify Factual Allegations Regarding Pre-Suit Notice Provided to Defendants (Counts V-VI).

Plaintiff's Opposition does not dispute that her breach of warranty claims premised on an alleged failure to provide an adequate warning must be dismissed under section 82.007(a) for the same reasons as her failure to warn claims. *Compare* Defs. Mem. at 17-18 *with* Opp'n at 12-13.

Plaintiff also does not dispute that the pre-suit notice requirement of Section 2.607(c)(1) applies to her breach of warranty claims. Opp'n at 12. While Plaintiff expends considerable effort outlining the policies behind the notice requirement, as well as what theoretically constitutes notice, Plaintiff's Opposition does not identify any allegations in her Complaint regarding the notice of the alleged breaches of warranty that she gave to Defendants prior to filing this lawsuit. Plaintiff's failure to plead pre-suit notice is fatal to her claims, and the Court should dismiss her warranty claims with prejudice. *See Elmazouni*, 220 F. Supp. 3d at 746 (collecting cases and dismissing breach of warranty claims for failure to plead pre-suit notice).

⁷ Because Plaintiff has not provided an argument as to the sufficiency of her negligence claim, her gross negligence claim must also fail. *See* Defs. Mem. at 16-17.

Additionally, Plaintiff argues that Defendants represented that Jardiance is a “safe and effective treatment for diabetes” and that these representations were made in “published labels and marketing materials . . . distributed to support and promote the sale of Jardiance.” Opp’n at 13 (citing Compl. ¶¶ 121, 123-24). But such conclusory allegations are insufficient to state plausible claims for breach of an express or implied warranty. *See* Defs. Mem. at 17-18 (collecting cases). Tellingly, Plaintiff cites no case law (or facts) in support of her argument that “the Complaint is rife with allegations of defendants’ express warranties, and Plaintiff and his physicians’ reliance on them.” Opp’n at 13.

e. Plaintiff’s Opposition Fails To Allege Her Fraud-Based Claims (Counts VII-VIII, X-XI) With Particularity.

Plaintiff concedes that, under Rule 9(b), she must allege her fraudulent misrepresentation, negligent misrepresentation, fraudulent concealment, and fraud claims “with particularity.” Opp’n at 13. Yet Plaintiff insists that her conclusory allegations concerning representations and omissions made by the collective “Defendants” are sufficient. *See id.* They are not, because Plaintiff has not alleged who at “Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Pharma GMBH [sic] & Co. KG, Boehringer Ingelheim International GMBH [sic], and Eli Lilly & Company,” Opp’n at 14, made the alleged fraudulent or negligent misrepresentations or omissions, requiring dismissal of her fraud-based claims. *See, e.g., Schouest v. Medtronic, Inc.*, 92 F. Supp. 3d 606, 611 (S.D. Tex. 2015), *appeal dismissed*, No. 15-40525 (5th Cir. Oct. 13, 2015) (dismissing fraud claims pursuant to Rule 9(b) where plaintiff failed to identify which of defendant’s employees made alleged fraudulent statements to physician).

Nor has Plaintiff identified the “what, when, where, and how” of the alleged fraudulent or negligent misrepresentations or omissions. Plaintiff attempts to point to allegations that supposedly plead “the content of defendants’ misrepresentations” in various “marketing and

promotional materials . . . labeling information, detail persons, seminar presentations, and regulatory materials” to which Plaintiff and/or her physician were allegedly exposed at some unspecified time after “Jardiance was approved in August 2014.” Opp’n at 14-15. These statements are entirely conclusory and do not identify the “particular statement” on which Plaintiff or her physician relied or the date when and place where any such statement was made. *Woodhouse*, 2011 WL 3666595, at *5. Because Plaintiff’s threadbare allegations do not satisfy Rule 9(b), all of Plaintiff’s fraud-based claims must be dismissed. *See* Defs. Mem. at 18-19.

IV. TEXAS DOES NOT RECOGNIZE PLAINTIFF’S CLAIMS FOR NEGLIGENT MISREPRESENTATION (COUNT VIII).

Plaintiff argues that she may recover for physical injuries arising from Defendants’ alleged negligent misrepresentations, citing two inapposite cases that each rely on the Restatement (Second) of Torts § 311 (1965). While § 311 defines a separate tort for negligent misrepresentation involving risk of physical harm, “Texas has not adopted Section 311 of the Restatement or otherwise created a tort for negligent misrepresentation leading to physical harm, rather than pecuniary loss.” *Roberts v. Zev Techs., Inc.*, No. 1:15-CV-309 RP, 2015 WL 7454688, at *5 (W.D. Tex. Nov. 23, 2015). Therefore, “the only relief for negligent misrepresentation available under Texas law is under Section 552B of the Restatement,” which requires a claim for pecuniary loss. *Id.* Because Plaintiff has made no such claim for pecuniary loss, her negligent misrepresentation claim must be dismissed with prejudice.

V. PLAINTIFF SHOULD NOT BE GRANTED LEAVE TO AMEND.

Defendants respectfully request that the Court grant their motion and dismiss the Complaint with prejudice. Because Plaintiff has not and cannot offer any facts supporting her Complaint and requested amendment, the Court should deny Plaintiff’s request to amend her factually deficient Complaint.

Dated: December 7, 2017

Respectfully submitted,

By: /s/ Jeffrey R. Lilly

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CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of December, 2017, a true and correct copy of the foregoing document was electronically filed with the Court through the CM/ECF system, which will send notification of such filing to all parties.

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